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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,727	02/05/2001	Matthew Stewart Platz	66-99A	6079

7590

05/29/2003

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EXAMINER

LIU, HONG

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 05/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/777,727

Applicant(s)

PLATZ ET AL.

Examiner

Hong Liu

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-59, 62 and 63 is/are pending in the application.
- 4a) Of the above claim(s) 1-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 62 and 63 is/are allowed.
- 6) ☐ Claim(s) 39-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

1. Claims 1-59, 62, and 63 are pending in this application.
- 2.

#### ***Continued Examination Under 37 CFR 1.114***

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 7, 2003 has been entered.

#### ***Election/Restriction***

During a telephone conversation with Ms. Susan Doughty on 03/04/02 a provisional election was made with traverse to prosecute the invention of Group II, claims 39-63. Claims 1-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 39-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following reason(s) apply:

The claims are not commensurate in scope as to the possibilities for the term “biologically active protein” in claim 39. The term is open-ended and all encompassing. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these broad claims, which embrace a diversity of biologically active proteins.

The nature of the invention in the instant application has claims which direct to a composition of comprising biologically active protein, blood, and blood constituents and a water soluble photosensitizer. The metes and bounds of the biologically active protein are unclear. There is no definition in the specification for the term except the mentioning that such a protein can be a therapeutic protein (see page 6). While examples on page 34 show that 7,8,10-trimethyl, 3-sulfonyl isoalloxazine can be used to neutralize microorganisms in blood, there is no teaching of the role of the biologically active protein in the neutralization of microorganisms in blood. The examples suggested that 7,8,10-trimethyl, 3-sulfonyl isoalloxazine alone is sufficient to neutralize microorganism in blood. Without the disclosure of the nature of the biologically active protein, one having ordinary skill in the art would have to undergo undue experimentation to determine which biologically active protein to use to practice the present invention.

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 40-59 are compound claims that are dependent from claim 39 which is a composition claim without a specific reference to a compound. It is unclear what the term "the compound" refers to.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

a person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35

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U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 39-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Goodrich et al. (US Patent 6,258,577). Goodrich teaches the use of alloxazines such as 7,8,10-trimethylisoalloxazine to inactivate microorganisms in fluids that contain biologically active protein, blood, and blood constituents by mixing the compounds with the material to be decontaminated (see cols. 3-6).

***Claim Rejections - 35 USC § 103***

Claims 39-59 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer et al. (US 3,920,650). Applicants tried to distinguish the reference by claiming a composition that contains blood product which the reference does not teach. However, it has brought to the Examiner's attention that the term "blood constituents" reads on water. For this reason, the amended composition claim is not blood-product specific and the composition of the present invention is patently indistinguishable from the composition in the reference, which is composed of water and the isoalloxazine compound.

Claims 39-59 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Petering et al. (US 2,825,729) for the same reasons give above.

Claims 39-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich et al. (US 6,258,577). The reference teaches methods of inactivating microorganisms in fluids

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which contain components selected from the group consisting of biologically active protein, blood and blood constituents. The methods comprise mixing non-toxic amount of an endogenous photosensitizers with the fluid. The photosensitizers useful in this invention include any photosensitizers (see cols. 3 and 4). The examples given in col. 5, lines 15-45 fall within the genus of the instant invention. The instant claims differ from the reference in that the claims are directed to a composition whereas the reference teaches the methods of inactivating microorganisms. However, the reference discloses that the practice of the method "requires mixing the photosensitizer with the material to be decontaminated. Mixing may be done by simply adding the photosensitizer or a solution containing the photosensitizer to a fluid to be decontaminated." (See col.6, lines 55-60). By following these instructions in the reference, one skilled in the art will obtain a composition that is the same as the one disclosed in the present application.

***Allowable Subject Matter***


Claims 62 and 63 are allowable.

7. Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the

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status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

Hong Liu  
May 22, 2003

  
**Mukund Shah**  
**Supervisory Patent Examiner**  
**Art Unit 1624**